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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,446	12/31/2003	Samuel Steinemann	1409-2 RCE/CON	1771

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Daniel A. Scola Jr.
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset,, NY 11791

EXAMINER	
MORILLO, JANELL COMBS	

ART UNIT	PAPER NUMBER
1793	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,446	STEINEMANN, SAMUEL	
	Examiner	Art Unit	
	Janelle Morillo	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/445675.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

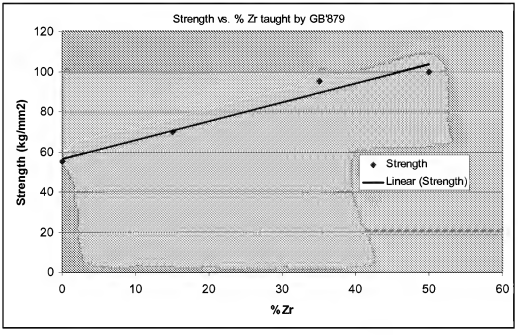
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 11, 14-15, 17-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,305,879 (GB'879).

GB'879 further teaches an example with 15% Zr obtains a moderate strength and high elongation (p 2 of GB'879). Broadly, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50). GB'879 teaches that up to 2% O_2 is typically present in "technically-pure titanium" and furthermore applicable to the alloys taught by GB'879, wherein said oxygen is present as an impurity or rigidity increasing addition (page 2 lines 75-79), which overlaps the presently claimed range of oxygen. The Ti-Zr alloy taught by GB'879 is a single phase alloy (see Ti-Zr phase diagram). Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Concerning claim 11, which mentions a TS of ≥ 769 MPa is achieved for a Ti-Zr alloy with 10-19% Zr, though GB'879 is drawn to binary Ti-Zr alloy with high amounts of Zr in order to obtain high strength, GB'879 teaches that the amount of added Zr is directly related to the strength achieved, and therefore is a result effective variable (wherein the expected result is increase in strength and decrease in elongation with increasing amounts of Zr, see Table p 2).



A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It would have been obvious to one of ordinary skill in the art to select the Zr amount/range and strength combination because GB'879 teaches a direct relationship between Zr and strength achieved, and wherein the instant strength minimum is expected to result from a Ti- Zr alloy within the instant range taught by GB'879 (see Table 2, Ti-15% Zr achieves a strength of 70 kg/mm2, Ti-35% Zr achieves strength of 95 kg/mm2, and

wherein Ti-19% Zr is expected to be in-between said strength values, which is approximately 75 kg/mm2. Though 75 kg/mm2 does not meet the instant minimum of >769 MPa= 78.4 kg/mm2, GB'879 teaches the strength of the alloys hot rolled and annealed alloys in said table can be further increased by about 30 kg/mm2 by cold working (p 2 lines 43-46). Therefore, the Ti-Zr alloy taught by GB'879 is held to produce the predictable result of moderate strength and elongation.

Concerning independent claim 11 (and dependent claim 19), GB'879 does not mention making said alloy by the presently claim process steps. However, GB'879 does mention the strength of the alloys can be further increased by about 30 kg/mm2 by cold working, and without elongations falling below 15% (p 2 lines 43-46). Further with regard to the instant product by process limitations, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art. See MPEP 2113, *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524) *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Because applicant has not shown that the Ti-Zr alloy product taught by GB'879 is materially different than the presently claimed product by process, it is held that GB'879 has created a prima facie case of obviousness of the presently claimed invention.

Concerning claims 14, 21, 23, as stated above, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy consists of 15% Zr balance Ti (see table on page 2), which overlaps the presently claimed alloying ranges.

Concerning claims 15, 17, 18, 22, 23, GB'879 teaches a titanium alloy suitable for medical implants (column 2 lines 80-86), wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr -wherein lowered ranges of Zr are expected to exhibit the *predictable result of moderate strength properties*. GB'879 teaches the corrosion and tissue compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65).

3. Claims 11, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB'879 in view of Chem. Ab. no. 103239 (hereinafter CA'239) and Davidson (US 5,169,597 A).

GB'879 is discussed above.

Concerning amended claims 16 and 20, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr -wherein lowered ranges of Zr are expected to exhibit the *predictable result of moderate strength properties*. GB'879 also teaches the corrosion and tissue compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65).

Concerning the process steps of independent claims 11, 16, 20, 22, GB'879 teaches that said Ti-Zr alloy is hot worked (such as forging, page 3 lines 6-7), annealed, and optionally cold worked (see page 2 Table and line 44). GB'879 does not mention a) the hot forging temperature range, or b) rapidly cooling after hot forging.

Concerning item a), CA'239 teaches that Ti-Zr alloys can be hot forged in the α as well as the $\alpha+\beta$ regions. Because CA'239 teaches a typical hot forging temperature range, and because CA'239 and GB'879 are both drawn to Zr containing Ti alloys, it would have been

obvious to one of ordinary skill in the art to hot forge the Ti-Zr medical implant alloy in the α as well as the $\alpha+\beta$ regions (as taught by CA'239) while performing the process as taught by GB'879 of hot forging, annealing, and optionally cold rolling.

Concerning item b), GB'879 does not mention rapidly cooling after hot forging. However, Davidson teaches that rapid cooling after hot working Ti alloys achieves a finer grain size (column 5 lines 21-25, rather than slow cooling) and provides adequate strength (column 3 lines 66-67). It would have been obvious to one of ordinary skill in the art to rapidly cool after hot working the alloy of GB'879, because Davidson teaches that a finer grain size can be achieved, rendering it more suitable for use as an implant material.

Concerning dependent claims 14, 15, 17-19, 21, 23, see discussion of GB'879 in paragraphs above.

Response to Arguments

4. In the response filed on June 30, 2008 applicant submitted various arguments traversing the rejections of record.

5. Applicant's argument that the present invention is allowable over the prior art of record because GB'879 teaches against the instant invention because GB'879 prefers Ti-Zr alloys with higher amounts of Zr in order to optimize strength, or that the prior art does not mention the combination of tensile strength and elongation at break, or that given the disclosure of GB'879 one would be motivated to select 50% Zr in order to maximize strength, has not been found persuasive. As stated above, though GB'879 is drawn to binary Ti-Zr alloy with high amounts of

Zr in order to obtain high strength, GB'879 teaches that the amount of added Zr is directly related to the strength achieved, and therefore is a result effective variable (wherein the expected result is increase in strength AND decrease in elongation with increasing amounts of Zr, see Table p 2). Changes in concentration or temperature will generally not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, i.e. they produce a new and unexpected result. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Because GB'879 teaches examples with increasing levels of Zr (15% Zr, 35% Zr) increase in strength but decrease in ductility, it would have been obvious to one of ordinary skill in the art to select the desired range of Zr based on said result effective variable of *combination* of strength and elongation (see also graph and discussion above).

6. Applicant's argument that the present invention is allowable over the prior art of record because GB'879 discloses only an alloy with a Zr content of between 25-75% can be used as surgical or dental implants and GB'879 contains no disclosure of an alloy for use in a surgical implant having the claimed Zr content has not been found persuasive. As stated above, GB'879 teaches a titanium alloy suitable for medical implants (column 2 lines 80-86), wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr -

wherein lowered ranges of Zr are expected to exhibit the *predictable result of moderate strength properties*. GB'879 teaches the corrosion and tissue compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65). Applicant has not shown unexpected biocompatibility (lack of retardation in the growth of cultured osteoblasts, etc) with respect to the prior art of record.

7. Applicant's argument that the present invention is allowable over the prior art of record because secondary references CA'239 and US 5,169,597 are not drawn to single phase alloys, and therefore are not combinable with GB'879, has not been found persuasive. CA'239 is relied on by the examiner to teach Ti-Zr alloys can be hot forged in the α as well as α+β regions, which is held to be applicable to Ti-Zr alloys containing said phases (wherein CA'239 and the instant invention both qualify). The exact temperature of said phase regions will vary slightly when amounts of other elements are added (which becomes apparent when looking at binary and ternary phase diagrams), but regardless, the teaching of forging in the α as well as α+β regions is still relevant. Davidson is relied on by the examiner to teach rapidly cooling creates a finer grain size, which is well known in the general art of metallurgy, and applicable to alloys with different phases.

8. Applicant's argument that the present invention is allowable over the prior art of record because the Ti15Zr alloy of GB'879 exhibits an inferior strength of 70 kg/mm2, which is lower than the presently claimed minimum of 78.4 kg/mm2 has not been found persuasive. GB'879 teaches the strength of the alloys hot rolled and annealed alloys in said table can be further increased by about 30 kg/mm2 by cold working (p 2 lines 43-46). Therefore, the Ti-Zr alloy taught by GB'879 further processed by cold working which GB'879 teaches increases the

strength by about 30 kg/mm2, is held to produce the predictable result of moderate strength and elongation, and meets the presently claimed strength minimum.

9. When the Examiner has established a *prima facie* obviousness, the burden then shifts to the applicant to rebut. *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc). Rebuttal may take the form of "a comparison of test data showing that the claimed compositions possess unexpectedly improved properties… that the prior art does not have, that the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes, or any other argument.. that is pertinent." Id. at 692-93; USPQ2d 1901. Applicant has not clearly shown specific *unexpected* results with respect to the prior art of record or criticality of the instant claimed range (wherein said results must be fully commensurate in scope with the instantly claimed ranges, etc. see MPEP 716.02 d).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 7:30 am- 4:00 pm Mon-Wed.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy King/
Supervisory Patent Examiner, Art Unit 1793

/J. M./
Examiner, Art Unit 1793
September 9, 2008

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/750,446	STEINEMANN, SAMUEL	
	Examiner	Art Unit	
	Janelle Morillo	1793	